9200/1624 DAC

Attorney Docket No. 053665-5005-02
Application S.N. 09/412,539

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#36

In re Application of: L.S. KUCERA et al	)	Confirmation No.: 9782
Application No.: 09/412,539	)	Group Art Unit: 1624
Filed: October 4, 1999	)	Examiner: B. Coleman
For: LIPID ANALOGS FOR TREATING VIRAL INFECTIONS	)	

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PETITION UNDER 37 CFR § 1.181
TO WITHDRAW A HOLDING OF ABANDONMENT

Sir:

Pursuant to the provisions of 37 C.F.R. §1.181, applicants hereby petition the Commissioner to withdraw the holding of abandonment (Notice of Abandonment mailed October 20, 2004, copy attached hereto) in the above-referenced application. The Examiner asserted reasons for abandonment, as stated on form PTO-1432 (copy attached hereto), is "Applicant failure to reply to the Office letter mailed on 24 December 2003."

Contrary to the Examiner's assertion, Applicants did respond to December 24, 2003 Office Action. Specifically, Applicants filed an amendment on March 22, 2004 (copy attached hereto for the Examiner's convenience). Moreover, a date-stamped postcard receipt (copy attached hereto) clearly shows that the U.S. Patent and Trademark Office ("USPTO") received the March 22, 2004 amendment.

Accordingly, Applicants hereby petition the Commissioner to withdraw the holding of abandonment for the above-identified application on the grounds that an amendment responding to the December 24, 2003 Office Action was timely filed in the USPTO on March 22, 2004.

Prompt and favorable action on the Petition is respectfully requested. In accordance with 37 C.F.R. § 1.17 it is believed that no fees are required at this time. Should any fees be required, however, please charge those fees to Morgan, Lewis & Bockius LLP deposit account no. 50-0310.

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

Dated: October 27, 2004

By: _____
Paul E. Dietze
Reg. No. 45,627

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,539	10/04/1999	LOUIS S. KUCERA	0044317U3	9782

28977 7590 10/20/2004

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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Abandonment	Application No.	Applicant(s)
	09/412,539	KUCERA ET AL.
	Examiner	Art Unit
	Brenda Coleman	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *24 December 2003*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

Brenda Coleman

Brenda Coleman
Primary Examiner
Art Unit: 1624

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

PLEASE STAMP AND RETURN TO SHOW RECEIPT OF:

In re APPLICATION of:
**INVENTOR: L. KUCERA *et al.*
Appln. No.: 09/412,539
Filed: October 4, 1999
FOR: LIPID ANALOGS FOR TREATING VIRAL INFECTIONS

Group Art Unit: 1624

Examiner: Brenda L. Coleman

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1. Amendment with authorization to charge to Deposit Account No. 50-0310 in the event the PTO deems a fee is necessary

Attorney Docket No.: 053665-5005-02
Dated: March 22, 2004

PED/ats

22

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: L. KUCERA *et al.*

Application No.: 09/412,539

Filed: October 4, 1999

For: LIPID ANALOGS FOR TREATING VIRAL INFECTIONS

Group Art Unit: 1624

Examiner: Brenda L. Coleman

Attorney Docket No.: 53665-5005-02

AMENDMENT

Box Non-Fee Amendment
Commissioner for Patents
P.O. Box 1460
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed December 24, 2003, Applicant respectfully requests that the following amendment and remarks to be entered into the record of the above-captioned application.

Amendments to the specification begin on page 2.

A complete listing of the currently pending claims begins on page 4

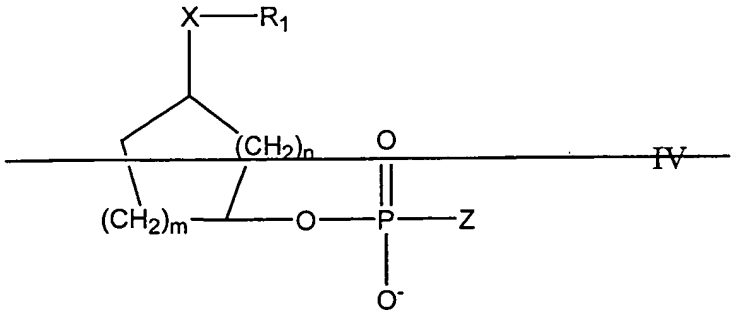
Remarks begin on page 6.

Conclusions begin on page 8.

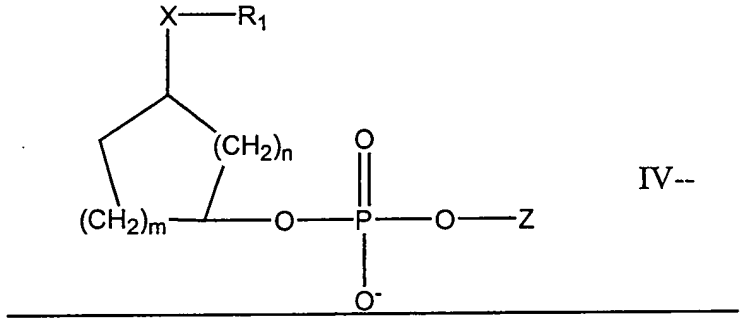
IN THE SPECIFICATION

Please amend the paragraph at page 5, lines 24-30 as follows:

-- A fourth aspect of the invention is a method of inhibiting viral infections comprising administering to a subject in need of such treatment an effective infection-inhibiting amount of a compound of Formula IV.



~~IV~~



IV--

Please amend the paragraph at page 21, lines 1-9 as follows:

--EXAMPLE 5

Preparation of 3'-azido-3'deoxy-5'-~~(dodecanamido-2-decoxypropyl)-phosphothymidine~~ (dodecanamido-2-decyloxypropyl)-phosphothymidine

~~3-Dodecanamido-2-decoxy-propanol~~ 3-Dodecanamido-2-decyloxy-propanol was synthesized via the scheme described in Morris-Natschke et al., ~~C.~~J. Med. Chem., **29**:2114 (1986). This alcohol was phosphorylated with diphenylchlorophosphate in pyridine to give the corresponding phosphate ester. The phenyl groups were then removed via hydrolysis with PtO_2. The phosphatidic acid derivatives were then conjugated to the 5'-hydroxyl of AZT (DCC condensation).--

Please amend the paragraph at page 21, lines 10-28 as follows:

--EXAMPLE 6

Preparation of 3'-azido-3'deoxy-5'-
~~**(dodecoxy-2-decyloxypropyl)-phosphothymidine**~~
(dodecyloxy-2-decyloxypropyl)-phosphothymidine

A. **3-Dodecyloxy-1,2-propanediol**[1]

Isopropylidineglycerol (solketal, 26.4 g, 0.20 mol) in 60 mL of toluene was added dropwise to a solution of powdered KOH (22.4 g, 0.04 mol) in 150 mL toluene. The resulting mixture was refluxed for 4 hours. 1-Bromodecane (50 g, 0.20 mol) in 40 mL of toluene was then added dropwise, and the solution was refluxed for 10 hours. After cooling, the reaction mixture was diluted with 200 mL of ice-water and extracted with diethyl ether (3 x 100 mL). The ether layers were dried over magnesium sulfate, and the solvent was removed *in vacuo*. The residue was dissolved in 60 mL of diethyl ether and 260 mL of MeOH. Concentrated HCl (60 mL) was added, and the solution was refluxed for 16 hours. After cooling, ice water (150 mL) was added, and the layers were separated. The aqueous layer was extracted with diethyl ether (2 x 75 mL). The combined organic fractions were then dried over sodium sulfate, filtered, and concentrated *in vacuo*. The solid residue was recrystallized from MeOH to give 37 g (0.14 mol), 71% of a white solid.--

[1] Section "A" titled "3-Dodecyloxy-1,2-propanediol" appears in the originally filed specification at page 21, line 13 as underlined text. Accordingly, the underlining presented here in this amendment, for this part of the specification, should not be construed as a change to page 21, line 13 of the specification.

IN.THE CLAIMS

This listing will replace all prior versions of listing of claims in the application.

Claims 1-55 (cancelled)

56. (previously amended) A method of combating a viral infection in a subject in need of such treatment, wherein the viral infection comprises a virus selected from the group consisting of HIV-1, HBV, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenze virus, the method comprising administering to said subject an effective infection-combating amount of a compound of 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine, or a pharmaceutical salt thereof.

Claims 57-68 (cancelled)

69. (original) A method according to Claim 56, wherein said viral infection is caused by HIV-1 virus.

70. (original) A method according to Claim 56, wherein said viral infection is caused by hepatitis B.

71. (original) A method according to Claim 56, wherein said viral infection is caused by herpes simplex virus.

Claims 72-106 (cancelled)

107 (currently amended) A method of combating a viral infection in a subject in need of such treatment, wherein the viral infection comprises a virus selected from the group consisting of HIV-1, HBV, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenze virus, the method comprising administering to said subject an effective infection-combating amount of a compound of ~~3'-azido-3'-deoxy-5'-(dodecyoxy-2-decyloxypropyl)-phosphothymidine~~ 3'-azido-3'-deoxy-5'-(dodecyloxy-2-decyloxypropyl)-phosphothymidine or a pharmaceutical salt thereof.

Claims 108-109 (cancelled)

110. (original) A method according to Claim 107, wherein said viral infection is caused by HIV-1 virus.

111. (original) A method according to Claim 107, wherein said viral infection is caused by hepatitis B.

112. (original) A method according to Claim 107, wherein said viral infection is caused by herpes simplex virus.

REMARKS

Claims 56, 69-71, 107, and 110-112 are pending in this application for the Examiner's review and consideration. Applicants appreciate the courtesy extended to Applicant's attorney, Paul E. Dietze, in an interview on March 5, 2004. The comments appearing herein are substantially in accordance with those presented and discussed in the interview.

The specification was amended, as suggested by the Examiner in the interview, to correct the structure of Formula IV at page 5, lines 24-30. Specifically, the structure of Formula IV was amended to include an oxygen atom between the phosphorous atom and the Z group (*See, e.g.*, Specification, page 11, lines 1-7). The specification was also amended to correct a typographical error in the names of the compounds synthesized in Examples 5 and 6. Specifically, Example 5 was amended to recite --decyloxypropyl-- rather than "decoxypropyl" and Example 6 was amended to recite --dodecyloxy-- rather than "dodecoxy."

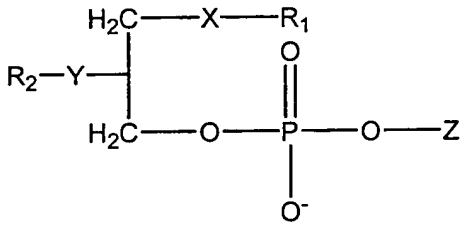
Claim 107 was amended, to be consistent with Example 6 of the specification, *i.e.*, to recite --dodecyloxy-- rather than "dodecoxy." No new matter has been added by these amendments so that their entry at this time is warranted.

THE REJECTION UNDER 35 U.S.C. § 101 AND 35 U.S.C. § 112. FIRST PARAGRAPH

Claims 56, 69-71, 107, and 110-112 were rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, for the reasons set forth on pages 2-4 of the Office Action. The Examiner rejected the claims under 35 U.S.C. § 101 alleging that the claims are not supported by either a specific asserted utility or a well established utility. The Examiner then further rejected the claims under 35 U.S.C. § 112, first paragraph, alleging that one skilled in the art would not know how to use the claimed invention since the invention is not supported by a specific asserted utility or a well established utility. Applicants respectfully traverse.

Applicants respectfully submit that claims 56, 69-71, 107, and 110-112 are supported by a specific asserted utility. Specifically, they are useful for treating viral infections (*See, e.g.*, Specification, page 11, lines 1-7). The above-mentioned claims are all directed to a method of treating viral infections using 3'-azido-3'-deoxy-5'-(dodecanamido-

2-decyloxypropyl)-phosphothymidine, *i.e.*, the compound of Example 5 (claims 56 and 69-71), or 3'-azido-3'-deoxy-5'-(dodecyloxy-2-decyloxypropyl)-phosphothymidine, *i.e.*, the compound of Example 6 (claims 107 and 110-112). Each of these compounds is a compound that falls within the class of compounds defined by Formula III.



III

wherein X, Y, Z, R_1, and R_2 are defined in the specification.

The Examiner, acknowledges that the specification satisfies the "how to make" prong of the utility requirement but alleges that the specification "does not satisfy the 'how to use prong' of utility for the compounds" (*See, e.g.*, Office Action, page 4). Applicants note, however, that the specification clearly states at page 11, lines 1-7 that compounds of Formula III, having an oxygen between the phosphorous atom and the Z group, have utility at "combating viral infection." Indeed, during the interview the Examiner acknowledged that the disclosure at page 11, lines 1-7 satisfies the "how to use prong" of the utility requirement for compounds of Formula III.

The Examiner also stated that when she entered the names provided in Examples 5 and 6 into ChemDraw, the resulting structure obtained by ChemDraw was not consistent with the structure of Formula III. The mere fact that the Examiner's ChemDraw program did not recognize the names used in Examples 5 and 6, however, does not mean that these names are inconsistent with the structure of Formula III or incorrect names for the compounds synthesized in these Examples. As discussed during the interview, there are many ways to name a compound. For example, even a simple compound like acetone has numerous names including, in addition to acetone, dimethylketone and 2-propanone. That the Examiner's ChemDraw program did not recognize the names used in Examples 5 and 6 simply means that ChemDraw uses a different system for naming compounds than the system that was used by the inventors. The nomenclature system used by the inventors, however, is not incorrect. Indeed, as noted at the interview, the system used by the

inventors to name the compounds synthesized in Example 5 and 6 of the specification is the same as the system used in a peer reviewed journal to name analogous compounds (*See, e.g., Antiviral Chemistry and Chemotherapy*, 9:157-165 (1998), which was submitted to the Examiner as part of the Declaration of Dr. L Kucera submitted with the amendment filed January 29, 2003). Accordingly, the nomenclature for the compounds synthesized in Example 5 and 6 are consistent with the structure presented in Formula III having an oxygen between the phosphorous atom and the Z group. For the above reasons, Applicants respectfully request that the rejection of claims 56, 69-71, 107, and 110-112 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

CONCLUSION

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

No fees are believed to be required for this submission. Should any fees be required, however, please charge those fees to Morgan, Lewis & Bockius LLP deposit account no. 50-0310.

Respectfully submitted,

Date March 22, 2004

Paul E. Dietze (Reg. No. 45,627)

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